

REMARKSRejection of Claims 14, 32, 34 and 36 Under 35 U.S.C. §112, First Paragraph

Claims 14, 32, 34 and 36 are rejected under 35 U.S.C. §112, first paragraph, because, according to the Examiner, the specification, while being enabling for carbohydrate, protein, fat and 5-hydroxytryptophan as an aid in the relief of symptomology associated with stress, does not reasonably provide enablement for caffeine as an aid in the relief of symptomology associated with stress.

Applicants respectfully disagree. As stated in MPEP §2164.08, when determining the subject matter encompassed by the claims, the Examiner should interpret what each claim recites and what the subject matter is when the claim is considered as a whole, not when its parts are analyzed individually (emphasis in original). In the instant application, the claimed invention is directed to a method of providing an individual with nutritional supplementation that aids in the relief of symptomology associated with stress resulting from serotonin-deficient disorders, comprising administering to an individual in need thereof a nutritional supplement comprising a low-glycemic-index carbohydrate, protein comprising alpha lactalbumin-enriched whey protein, fat, caffeine and, optionally, 5-hydroxytryptophan (5-HTP), in amounts that together work to manage symptoms associated with stress.

The instant application teaches that “long-term administration of the nutritional supplement of the invention may aid in the reduction of health risks associated with chronic stress, such as diminished mental and physical performance...” (see page 15, lines 14-16). Applicants go on to teach that caffeine improves long-term cognitive performance, mood, and alertness in well-rested and sleep-deprived individuals without side effects (see page 10, lines 17-18). Thus, caffeine is included in the nutritional supplement in an amount that works together with the other ingredients to manage the symptoms associated with stress.

Based upon the objective of the claimed invention, one of skill in the art would understand caffeine’s role in a nutritional supplement for the management of symptomology associated with stress resulting from serotonin-deficient disorders in an individual in need thereof. Thus, the skilled artisan would be enabled to practice the invention without undue experimentation. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 14, 19, 21, 23-26, 28, 30 and 32-41 Under 35 U.S.C. §103(a)

Claims 14, 19, 21, 23-26, 28, 30 and 32-41 are rejected under 35 U.S.C. §103(a) as being unpatentable over Bell *et al.* (USPN 5,968,896) ("Bell") in view of Pollack (USPN 4,853,377). According to the Examiner, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have added the tryptophan plus calcium of Pollack to the nutritional supplement of Bell in order to reduce stress, as described by Bell, column 2, 36-37.

Applicants respectfully disagree. Neither Bell nor Pollack, alone or in combination, teach or suggest a method of providing an individual with nutritional supplementation that aids in the relief of symptomology associated with stress resulting from serotonin-deficient disorders, comprising administering to an individual in need thereof a nutritional supplement comprising a low-glycemic-index carbohydrate, protein comprising alpha lactalbumin-enriched whey protein, fat, caffeine and, optionally, 5-hydroxytryptophan (5-HTP), in amounts that together work to manage conditions associated with stress.

It is the object of Bell to provide a nutritional supplement that is rich in calories and contains ingredients that have been shown to enhance/stimulate immune function. The nutritional supplements of Bell are ideal for patients who are about to undergo major gastrointestinal or non-cardiac thoracic surgery, due to the high post-operative incidence or risk of infection. Bell neither teaches the symptomology associated with stress nor the management of symptomology associated with stress resulting from serotonin-deficient disorders in an individual in need thereof.

To maintain a rejection based on obviousness, it must be demonstrated that at the time of the invention, one of skill in the art would have been motivated to combine the data of Bell and Pollack to produce Applicants' claimed invention with a reasonable expectation of success. See *In re Vaack*, 20 U.S.P.Q. 2d 1438, 1442 (Fed. Cir. 1991). Pollack fails to provide this necessary motivation.

As discussed above, Bell does not provide the teachings for a method of providing an individual with a nutritional supplement for management of symptomology associated with stress resulting from serotonin-deficient disorders in an individual in need thereof. Furthermore, Pollack does not provide that which Bell lacks. Rather, Pollack describes a dietary therapeutic

composition that seeks to increase both the level of serotonin within the brain and the quality and strength of the nerve signals or impulses transmitted by serotonin is improved and strengthened. Pollack teaches that this is achieved because a major aspect of the invention described therein is specifically directed to the addition of a salicylate, calcium, magnesium and ascorbic acid, as well as other ingredients, to a tryptophan-based composition (see col. 3, lines 54-60).

Pollack teaches that these ingredients are added to the composition because the conversion of tryptophan to serotonin is a two-step enzymatic process. First, tryptophan must be converted into 5-hydroxytryptophan (5-HTP) via interaction with the enzyme tryptophan hydroxylase. The second step involves the decarboxylation of 5-HTP into 5-HT via aromatic amino acid decarboxylase (see col. 4, lines 1-7). Pollack goes on to state that it is believed that the first step presents the greatest hurdle in the conversion of tryptophan to serotonin because this step primarily affects the amount of serotonin produced within the brain (see col. 4, lines 8-13).

Because Pollack believes that the first enzymatic step is an obstacle, Pollack teaches a composition that attempts to overcome this obstacle. According to Pollack, calcium is added to the composition because, among several reasons, calcium stimulates the kinase to phosphorylate tryptophan hydroxylase which, as discussed above, converts tryptophan to 5-HTP (see col. 4, lines 20-25). Pollack goes on to state that ascorbic acid is added to the composition because it is a hydrolase cofactor which is required for the hydroxylation of L-tryptophan to 5-HTP (see col. 7, lines 44-46). Pollack teaches that magnesium is added to the composition because its presence increases the number of serotonin binding sites in the nerve synapse and increases the strength of the bonds between the serotonin and the nerve cells resulting in stronger and clearer transmission of nerve signals (see col. 7, lines 34-42). Furthermore, Pollack states that the addition of salicylate to the composition is crucial because salicylate displaces tryptophan from its protein binding site on albumin in blood plasma thereby raising the free, circulating tryptophan concentration in the blood (see col. 9, lines 21-33)(emphasis added). Moreover, Pollack teaches that copper (see col. 7, lines 61-66), niacinamide (see col. 8, lines 24-36), carbohydrates (see col. 8, lines 54-65) and pyridoxine (vitamin B₆)(see col. 8, lines 39-45) can be, and are, added to the composition. Nowhere does Pollack teach the symptoms that are associated with stress in individuals resulting from a serotonin-deficient disorder or what ingredients might be incorporated into the dietary supplement to address those other symptoms.

Thus, the object of Pollack's invention is to provide a tryptophan-based composition, in combination with other ingredients, and a method for facilitating the brain's synthesis of serotonin. Pollack goes on to teach that the unpredictable results achieved by prior tryptophan-based compositions may be attributable to a lack of ascorbic acid, calcium and/or magnesium available in the patient's brain for the conversion of tryptophan to serotonin (see col. 5, lines 3-7). One or all of the ingredients taught by Pollack are required to be part of the composition. However, these ingredients are not part of Applicants' nutritional supplement. Based on the teachings of Pollack, one of skill in the art would not be motivated to prepare a nutritional supplement lacking the ingredients taught by Pollack with a reasonable expectation of success that the supplement would result in an increase in serotonin. Therefore, Pollack teaches away from Applicants' claimed invention.

Bell and/or Pollack, alone or in combination, do not teach or suggest Applicants' claimed invention, thus, one of skill in the pertinent art, upon reading Bell and Pollack, would not be motivated to modify the teachings therein to obtain the claimed invention. As such, the claimed invention would not have been obvious to the skilled person in view of the prior art. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (978) 341-0036.

Respectfully submitted,
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